REMARKS

This amendment is in response to the Office Action dated July 11, 2008. A Petition for Extension of Time under 37 CFR 1.136(a) (three months) is also enclosed, along with a Request for Continued Examination (RCE) pursuant to 37 CFR 1.114 (RCE). A Power of Attorney and a Statement under 3.73(b), empowering the undersigned to file this amendment on behalf of the assignee, are being filed concurrently with this amendment; copies of these documents are enclosed. Entry of this Amendment and reconsideration of this application are respectfully requested.

Claim Rejections under 35 USC 103(a)

Claims 1-8, 10 and 11 were rejected as obvious in view of a patent publication to Kienzle, III ("Kienzle") in combination with a patent publication to White ("White").

Independent claims 1, 5, 9 and 11 have been amended to better clarify their differences with respect to the cited art. Each is discussed below in turn.

Claim 1

Claim 1 is directed to a computer assisted, non-radiological method of intra-operatively measuring and assessing relative geometric relationships among skeletal features of a hip joint, suitable for surgical navigation of a hip arthroplasty operation. As amended, the method of claim 1 requires:

- defining a pelvic plane without reference to previously obtained radiological data by touching, with a trackable probe, at least three superficial points corresponding to respective recognizable anatomic features of the pelvis and tracking the probe with a locating system;

- tracking with the locating system the orientation of an acetabular implant tool which is coupled to an acetabular implant, to obtain acetabular implant orientation data;
- adjusting the acetabular implant into a desired orientation with respect to the defined pelvic plane, without reference to previously obtained radiological data, by relating the acetabular implant orientation data to the defined pelvic plane;
- touching, with a trackable probe, at least three points on the acetabular implant and tracking the probe with the locating system;
- based on the tracked locations of the at least three points on the acetabular implant, calculating an orientation of the acetabular implant; and
- comparing the calculated orientation of the acetabular implant to the desired orientation to verify proper orientation of the acetabular implant.

Support for the amendments to claim 1 can be found in the specification as follows:
- defining a pelvic plane without reference to previously obtained radiological data -- page 5, lines 22-29;
- by touching, with a trackable probe, at least three superficial points corresponding to respective recognizable anatomic features of the pelvis and tracking the probe with a locating system - page 17, line 26 -- page 18, line 7;
- tracking with the locating system the orientation of an acetabular implant tool which is coupled to an acetabular implant, to obtain acetabular implant orientation data -- page 23, lines 14-25;
- touching, with a trackable probe, at least three points on the acetabular implant and tracking the probe with the locating system,

and based on the tracked locations of the at least three points, calculating an orientation of the acetabular implant -- page 25, line 17 - page 26, line 18.

A major distinction between the method of claim 1 and that described in Kienzle is that the probe/marker-related steps of Kienzle's method are performed by manipulating the image of a virtual probe on a screen displaying previously acquired x-rays. An example of this is described in Kienzle in his paragraph 45:

" . . . In the preferred embodiment, shown in FIG. 8, two modified AP x-ray images (171 and 172) of the patient's pelvis (181) are acquired by the C-arm fluoroscope and shown on the display (170). The first image (171) is an "inlet view" of the pelvis (181) taken with the C-arm aimed obliquely, approximately 40 degrees, from cephalad and anterior to caudal and posterior. The second image (172) is an "outlet view" of the pelvis (181) taken with the C-arm aimed from caudal and anterior to cephalad and posterior. The surgeon then uses a probe (150) outfitted with localizing emitters (177) to identify three landmarks (182, 183 and 184) by positioning the probe (150) in such a manner that the virtual probe tip (156) overlays the image (173) of the first bony landmark (183) in both views (171, 172) . . .".

Thus, Kienzle's method first requires the acquisition of x-ray images while the patient is on the operating room table, which is costly and time-consuming, and exposes the patient and potentially the surgeon to radiation. Then, with the images acquired and displayed, a virtual probe tip is positioned to identify bony landmarks on the displayed images.

In contrast, the amended claim 1 requires that probe/marker steps of the applicants' method be performed without reference to previously obtained radiological data, thereby enabling the drawbacks noted above with respect to the acquisition of x-ray images to be avoided.

In addition, Kienzle fails to disclose numerous additional elements of the amended claim 1, including those listed below:

- defining a pelvic plane without reference to previously obtained radiological data by touching, with a trackable probe, at least three superficial points corresponding to respective recognizable anatomic features of the pelvis and tracking the probe with a locating system.

Kienzle's method employs a virtual probe, which never actually touches any anatomical features, and requires previously obtained radiological data.

- adjusting the acetabular implant into a desired orientation with respect to the defined pelvic plane, without reference to previously obtained radiological data, by relating the acetabular implant orientation data to the defined pelvic plane.

Kienzle's method requires previously obtained radiological data.

- touching, with a trackable probe, at least three points on the acetabular implant and tracking the probe with the locating system;
- based on the tracked locations of the at least three points on

the acetabular implant, calculating an orientation of the acetabular implant; and

- comparing the calculated orientation of the acetabular implant to the desired orientation to verify proper orientation of the acetabular implant.

The applicants believe that there is some confusion with respect to these elements, which were introduced in the response to the first Office Action. These steps are described on page 25, starting at line 17, as follows:

"The orientation of the implant shell 93 is preferably next verified (step 204) by touching at least three points on the rim of the acetabular implant shell 93 with the tip 52 of probe 50 and inputting the three positions via the locating system 26. The three or more points are used by the computer to define the plane of the shell opening, which is normal to a vector 172...."

Note that these steps are performed in addition to the step of tracking the acetabular implant tool, and provide additional verification that the implant is correctly positioned.

These additional steps are not disclosed in the Kienzle reference. Kienzle does disclose tracking an acetabular implant tool, as shown in his FIG. 9. However, Kienzle fails to perform a verification step as defined by these elements of claim 1 - i.e., he never discloses touching at least three points on the acetabular implant using a trackable probe, tracking the probe with the locating system, calculating the acetabular implant's orientation, or comparing the calculated orientation to the desired orientation to verify proper orientation. Performing these steps, as required by claim 1, has the advantage of detecting insecure installation or

slippage of the implant relative to the pelvis which might otherwise occur after the trackable implant-bearing tool is removed. The applicants are not aware that this problem or the need for verification is disclosed in the prior art, or anywhere except in the applicant's disclosure.

In summary, Kienzle fails to disclose or suggest many of the essential elements of the amended claim 1.

A patent publication to White is cited for the "locating at least three points" element of the amended claim 1. However, as with Kienzle, White does not disclose touching at least three points on the acetabular implant with a trackable probe. The Examiner refers to paragraphs 60-62 of White, which reference his FIG. 14. But as is clear from referring to FIG. 14 and its accompanying text, White does not touch any points on the acetabular implant with a trackable probe, and he has no receivers mounted on the implant.

Therefore, even if combined as suggested by the Examiner, Kienzle and White fail to disclose many of the essential elements of the amended claim 1. As such, the applicants assert that claim 1 would not have been obvious in view of Kienzle and White at the time the invention was made, and should therefore be allowable.

Claims 2-4

Claim 2 has been canceled.

The amended claim 1 is the parent of claims 3 and 4, each of which should therefore be allowable along with claim 1.

In addition, claim 4 has been amended to further clarify its

differences with respect to the cited art. As amended, claim 4 explicitly requires that its pelvic marker reference system be defined without reference to previously obtained radiological data, in contrast to the x-ray based method of Kienzle. Furthermore, the trackable marker on the pelvic bone is required to have at least three optical tracking references, as opposed to the single hard-wire electromagnetic receiver taught by White.

For these reasons, the applicants assert that claim 4 should be found to be allowable over the cited art on its own merits.

Claim 5

Claim 5 is directed to a method of determining changes between pre-operative and post-operative relationships between a femur and a pelvis, suitable for use during a hip arthroplasty operation. As noted above, claim 5 has been amended to better clarify its differences with respect to the cited art. As amended, the method of claim 5 requires:

- maneuvering the femur into a natural reference position;
- securing a trackable marker having at least three optical tracking references to the femur by gripping the femur without penetrating through the outer cortical shell of the femur;
- measuring, by optically tracking the trackable marker with a non-radiological locating system, pre-replacement femoral parameters in relation to the pelvis;
- after implanting a prosthetic, returning the femur to the natural reference position;
- again measuring, by optically tracking the trackable marker with a non-radiological locating system, post-replacement femoral parameters in relation to the pelvis; and
- comparing the pre-replacement and post-replacement parameters in

a computer model.

Support for the amendments to claim 5 can be found in the specification as follows:
- natural reference position -- page 20, lines 16-19;
- trackable marker having at least three optical tracking references -- FIG. 5;
- optically tracking the trackable marker with a non-radiological locating system -- page 5, lines 9-21.

There are a number of substantial distinctions between the method recited in the amended claim 5 and those which are disclosed in Kienzle and White. For example, though Kienzle makes a passing reference to tracking the femur in his paragraph 0038, Kienzle fails to disclose these claim 5 elements:

- maneuvering the femur into a natural reference position, and returning the femur to the natural reference position.

Kienzle describes tracking the pose of the bone during the procedure, but does not disclose making and comparing measurements made with the femur in an initial natural reference position and after the femur has been returned to the reference position, as required by claim 5.

- securing a trackable marker having at least three optical tracking references to the femur by gripping the femur without penetrating through the outer cortical shell of the femur.

Kienzle discloses attaching a marker using one or more screws (see paragraph 38).

- measuring, by optically tracking the trackable marker with a non-radiological locating system, pre- and post-replacement femoral parameters in relation to the pelvis.

As noted above, Kienzle method requires the use of a screen displaying previously acquired x-rays, and thus does not use a non-radiological locating system.

In summary, Kienzle fails to disclose or suggest many of the essential elements of the amended claim 5.

With respect to White, it should be noted that White fails to disclose these elements of claim 5:

- maneuvering the femur into a natural reference position, and returning the femur to the natural reference position. "Natural reference position" is defined in the specification at page 20, lines 16-19:

"After finding the native head center, the physician disposes the femur in a natural reference position ("Position 1"), preferably aligned with the patient's spinal axis, . . .".

Thus, the "natural reference position" of claim 5 is an absolute position.

In contrast, in his paragraph 0058, White discloses placing the pelvis and femur in an "initial relative position", rather than in an absolute natural reference position as specified by claim 5.

- securing a trackable marker having at least three optical tracking references to the femur by gripping the femur without

penetrating through the outer cortical shell of the femur.

White discloses affixing a single electromagnetic receiver to the femur, which is connected by wire to a processing system (14). He neither discloses nor suggests the use of a marker having at least three optical tracking references as specified in claim 5.

- measuring, by optically tracking the trackable marker with a non-radiological locating system, pre- and post-replacement femoral parameters in relation to the pelvis. This arrangement provides advantages in that no wires are required between the marker and the locating system, and the use of at least three optical tracking references enables the locating system to determine the spatial location of the femur in three dimensions.

White discloses an electromagnetic receiver system. As illustrated, for example, in FIG. 18, a single receiver is affixed to the head of the femur, and connected by wire to the processing system. No optical tracking is disclosed.

Therefore, even if combined as suggested by the Examiner, Kienzle and White fail to disclose many of the essential elements of the amended claim 5. As such, the applicants assert that claim 5 would not have been obvious in view of Kienzle and White at the time the invention was made, and should therefore be allowable.

Claims 6-7

The amended claim 5 is the parent of claims 6 and 7, which should therefore be allowable along with claim 5.

Claim 8

Claim 8 is directed to a system for measuring and assessing

the skeletal geometry of a hip joint during surgery, suitable for surgical navigation of a hip arthroplasty operation. As noted above, claim 8 has been amended to better clarify its differences with respect to the cited art. As amended, the system includes:

- a locating system which determines positions and orientations of optically trackable markers;
- a computer, interfaced to the locating system to receive tracking data, and calculating from said tracking data the positions of tracked objects in relation to a generic computer model of a patient's hip geometry;
- a software module, executable on the computer, which defines the patient's pelvic plane without reference to previously obtained radiological data, by locating at least three pelvic landmarks;
- a pelvic tracking marker having at least three optical tracking references, fixable to the pelvic bone and optically tracked by the locating system, to track in real time the orientation of the pelvic plane;
- a femoral tracking marker having at least three optical tracking references, securely attachable to a femur of the patient and optically trackable by the locating system to detect changes in leg length and femoral offset; and
- a non-penetrating means for securing the femoral tracking marker to the femur of the patient.

Support for the amendments to claim 8 can be found in the specification as follows:

- a locating system which determines positions and orientations of optically trackable markers -- page 10, lines 6-8;
- a pelvic tracking marker having at least three optical tracking references -- FIG. 5;

- a femoral tracking marker having at least three optical tracking references -- FIG. 4.

There are a number of substantial differences between the system recited in the amended claim 8 and those which are disclosed in Kienzle and White. For example, Kienzle fails to disclose these claim 8 elements:

- a locating system which determines positions and orientations of optically trackable markers without reference to previously obtained radiological data.

As noted above, Kienzle's system employs a screen displaying previously acquired x-rays, and thus does not use a non-radiological locating system as required by claim 8.

- a software module, executable on the computer, which defines the patient's pelvic plane without reference to previously obtained radiological data, by locating at least three pelvic landmarks.

Though Kienzle does disclose defining a pelvic plane, he does so using a virtual probe, imaged on a screen displaying x-ray images of the patient's pelvis acquired by a C-arm fluoroscope (see paragraph 45). Kienzle does not disclose defining the pelvic plane without reference to previously obtained radiological data, as explicitly required by claim 8.

- a non-penetrating means for securing the femoral tracking marker to the femur of the patient.

As noted above, Kienzle attaches his marker using one or more screws.

White is said to teach a non-penetrating means for securing a femoral tracking marker. However, White does not disclose a femoral tracking marker having at least three optical tracking references which are optically trackable by the locating system, as required by claim 8. Rather, White discloses affixing a single electromagnetic receiver, which is hard-wired to the processing system, onto the head of the femur.

White also fails to disclose these elements of claim 8:

- a locating system which determines positions and orientations of optically trackable markers.

White uses electromagnetic receivers which are hard-wired to a processing system.

- a software module, executable on the computer, which defines the patient's pelvic plane without reference to previously obtained radiological data, by locating at least three pelvic landmarks.

White discloses nothing of this sort.

- pelvic and femoral tracking markers each having at least three optical tracking references and optically tracked by the locating system.

As noted above, White discloses affixing single electromagnetic receivers in various locations, each of which is hard-wired to a processing system.

Therefore, even if combined as suggested by the Examiner, Kienzle and White fail to disclose many of the essential elements of the amended claim 8. As such, claim 8 would not have been obvious in view of Kienzle and White at the time the invention was

made, and should therefore be allowable.

Claims 9-11

Claim 9 has been canceled.

The amended claim 8 is the parent of claims 10 and 11, which should therefore be allowable along with claim 8.

New claim

New claim 12, dependent from claim 10, has been added. The requirements of claim 12 are similar to the acetabular implant orientation verification steps of claim 1. As noted in the discussion of claim 1, nothing resembling this implant orientation verification functionality is disclosed in any of the cited art.

All of the claims presently in the application are believed to be patentably distinct with respect to the cited art and to otherwise be in proper form for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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